REQUEST FOR APPLICATIONS (RFA)

MSCRF Clinical Program

INTRODUCTION:

Stem cell research offers extraordinary promise for new medical therapies and a better understanding of the devastating diseases of our time. The development of new medical strategies for the prevention, diagnosis, treatment and cure of human diseases, injuries and conditions through human stem cell research is a high priority for the State of Maryland.

FUNDING OBJECTIVES

In this Request for Applications, the MSCRF is soliciting Clinical Stem Cell Research Grant Applications from organizations that wish to conduct clinical trials in the State of Maryland using human stem cells to advance medical therapies. It is also the intent of the Program to foster collaborations between various schools, departments, and institutions within academic research organizations, and between public and private sectors. Grants awarded under this RFA will fund clinical research projects involving human stem cells, stem cell derivatives (including extracellular vesicles and secretome), or other technologies enabling or supportive of human stem cells.

ELIGIBILITY INFORMATION

Organizations that meet the in-State eligibility requirements specified below, and evidence the skills, experience, resources and support necessary to carry out the proposed research may apply for a Clinical Research Grant.

Universities, not-for-profit research organization, for-profit, public or private organization or companies of all types are eligible for this Award (i.e., those affiliated with universities, colleges, research institutes, medical centers and laboratories as well as those that operate independently).

Organizations, including but not limited to companies, eligible for Clinical Research Grants must conduct all MSCRF-funded work in the State of Maryland.

Organizations conducting Clinical research may be based outside of Maryland, but the work funded by the MSCRF must be conducted at a clinical trial site in Maryland.

Companies and/or Principal Investigators (PIs) that have received prior MSCRF funding may apply for this Award on a related or different topic. A summary of the research progress must be included under Section III, subsection 3 of the Application (Clinical potential and/or Plan) if the Research Project (defined below) is related to the technology previously funded by MSCRF. Any publication and/or presentation that resulted from the previous MSCRF funding must be included in the Scientific Literature (Section III, subsection 8) of the Application.

Each Application for an Award funded by the MSCRF shall have only one (1) PI, but may have multiple Co-PIs, Investigators and/or collaborators. PIs may participate as collaborators in any number of MSCRF-

funded Projects in the same funding cycle. However, they may apply to the MSCRF as the **lead PI for only one new Award in any given cycle**.

Companies owned by women, underrepresented minorities and individuals with disabilities are encouraged to participate in this program.

ELIGIBLE RESEARCH AND CELL TYPES:

Only applications with a research proposal ("Research Project") that include clearly defined and achievable milestones will be considered for review.

All research funded by the MSCRF must involve human stem cells. All types of human stem cells, as defined in the Stem Cell Act, are eligible without preference. The Stem Cell Act defines eligible human stem cells as follows: A human cell that has the ability to: (1) divide indefinitely; (2) give rise to many other types of specialized cells; and (3) give rise to new stem cells with identical potential. The full text of the Stem Cell Act is available on the MSCRF Web site (see www.MSCRF.org).

OTHER ELIGIBILITY CRITERIA

Applications that involve a clinical trial must have an IND or IDE, cleared by the FDA for the therapy or device under study before the Application is submitted to the MSCRF for review.

Awardees shall receive MSCRF funds only after providing documentation to MSCRF confirming that the research to be conducted with MSCRF funds has been approved by the relevant Institutional Review Board ("IRB"), Institutional Animal Care and Use Committee ("IACUC") and, for Projects involving human pluripotent stem cells, a Stem Cell Research Oversight Committee ("ESCRO/SCRO").

AWARD INFORMATION

AVAILABLE FUNDS

The MSCRF is currently budgeted to commit up to $16.05 million, in aggregate, in FY 2027 to fund Grants under all of its RFAs. The number of Grants awarded will depend upon the quality, size and mix of Applications received.

Because the nature and scope of the proposed research will vary from Application to Application, the size and duration of Awards may also vary. Approved Projects may be funded at or below the requested/proposed amount, for a number or reasons, including potential reductions in State appropriations or funding otherwise available to MSCRF.

AWARD SIZE, DURATION & TERMS

Under this RFA, the total direct costs proposed may not exceed $1,000,000 for a maximum of 2 years.

Clinical Projects shall require a 1:1 match of non-state money. Indirect costs are not allowed under this RFA.

Under this RFA, MSCRF Grant Award funds may be used for the following direct costs, commensurate with the time dedicated solely to the proposed research:

- Salary and fringe benefits for the PI and essential personnel
- Equipment
- Supplies
- Consultant costs

- Contract services
- Collaboration expenses
- Travel and conference expenses (capped at $5000; international travel is not an allowable expense)
- Publications and miscellaneous costs

MSCRF funds may not be used to cover personnel costs of Investigators who are located and conduct the work outside the State of Maryland, regardless of whether such out-of-State Investigators are employed or retained by a Maryland-based or non-Maryland based organization.

Purchase of equipment and supplies, publication costs, conference expenses, contract manufacturing and services and other non-personnel costs may be incurred outside the State of Maryland, in accordance with customary practices of researchers.

Once a Grant has been awarded, up to ten (10) percent of funds can be reallocated between budget categories without prior MSCRF approval (e.g., from salaries to supplies). However, reallocations in excess of ten (10) percent must be approved in advance by MSCRF.

SHARING RESEARCH RESULTS AND PUBLISHING

Applicants must commit to making the results of their MSCRF-funded research readily available to others, through publications (preferably), public presentations or other accessible means.

COMPLIANCE

A Company and/or PI not in compliance with the reporting obligations under the Clinical Research Grant shall not be eligible to apply for continued or subsequent MSCRF funding.

APPLICATION INFORMATION

DEI REGISTRATION

Pursuant to its enabling legislation, TEDCO is required to foster inclusive and diverse entrepreneurship and innovation throughout Maryland. Accordingly, TEDCO is now collecting race, gender, and ethnicity data, to better understand the communities that are accessing MSCRF resources/funding. This data will not be accessible to MSCRF/TEDCO program/fund managers and will only be provided to them in an aggregated (anonymous) form. The data will not be used for funding consideration.

CONTENT & FORMAT OF APPLICATION

All Sections of the Application must be submitted through the MSCRF online submission system. The document must be formatted using point size 12 Arial font with margins no smaller than one-half (0.5) inch on all sides and uploaded in a PDF format using the instructions in the portal. Applications not meeting the minimum requirements will be rejected without further consideration and the Applicant will be so notified. Information or documents submitted after the Application Submission Deadline will not be accepted, included, or considered in the review of the Application.

APPLICATION COMPONENTS

The intent of the Application is to provide enough information so a panel of reviewers can effectively evaluate the merit of the Research Project. Application must include the following information:

Section I. Title of the Research Project

Section II. Web form Questions: Applicant must respond to the following questions:

- New application or resubmission and the prior application number(s) for prior MSCRF applications
- Proposed period of performance for the Research Project
- The total amount of funding requested
- IP status- whether there is a pending or issued patent application (s) directed to the Research Project
- Type of stem cell type that will be used for Research Project
- List the disease indication and disease category for the Research Project
- List Keywords for the Research Project (100 characters limit)
- Short non-confidential summary of the Research Project. If awarded, this information becomes public. Do not include any confidential or proprietary information. (1800 characters limit)
- Public Health Impact Statement: 2-3 sentences on public health impact. If the Research Project outcome will inform the development of a product that serves medically underserved communities or a rare disease, please also specify. (500 characters limit)
- Bioethics statement: describing the ethical issues relevant to the proposed research and how these issues will be addressed, including, but not limited to, a discussion of the ethical issues related to the cell type(s) and cell line(s) to be used; animal welfare (i.e., IACUC); IRB review and related concerns regarding human subjects, if applicable. (3000 characters limit)
- Impact on Biotechnology in Maryland. Describe the potential of this application to impact the biotechnology sector in the state of Maryland. Some examples may include IP that may be licensed or lead to commercialization, existing or proposed collaborations, creation of new jobs, and workforce development. (1800 characters limit)
- PI Areas of scientific expertise (100 characters limit)
- PI Primary research focus (500 characters limit)
- Areas of potential collaboration that the PI is seeking (500 characters limit)
- Indicate the PI's previous experience as an MSCRF applicant and provide the application number if previously funded.
- Enter the URL address of your laboratory/company website.

Section III. Attachments: Ensure strict adherence to the page limits. Incompliance with the application requirements will result in disqualification.

1. **Research Project Summary - Limited to one (1) page.**
   Summary of the Research Project describing the proposed research and its potential contribution toward the goals of the MSCRF and this RFA, as set forth in this document.

2. **Clinical Research Plan - Limited to eight (8) pages, including all tables, figures, and charts.**
   An overall plan for development of the therapeutic candidate, including (1) A description of the targeted disease, condition or injury and the potential impact that the proposed therapy will have, if successfully commercialized, on the treatment or progression of that disease, injury or condition, or on medical practice; (2) An explanation of why human stem cells are necessary or advantageous to the proposed research; (3) The Research Design, including the Scientific Rationale, Experimental Approaches, Methods and Technique proposed for accomplishing the Project goals within two (2) years.; and (4) If applicable, a Target Product Profile for the therapeutic candidate. Each of the

following aspects of a TPP should be addressed: (a) description; (b) significance; (c) indication(s); (d) activity (in vitro/in vivo) and efficacy endpoint (in patients); (e) safety; (f) route; (g) regimen; (h) risk versus benefit and (i) clinical competitiveness. For proposed allogeneic cell therapies, immune tolerance or immunosuppression strategies should be addressed in the above sections.

3. **Clinical Potential and/or Plan - Limited to two (2) pages.**
   An explanation of (i) how clinical practice and treatment of human diseases, conditions or injuries will be advanced by the proposed research; (ii) how the proposed research may contribute to new medical treatments or interventions; (iii) A summary of the research progress must be included if the Research Project (defined below) is related to the technology previously funded by MSCRF; (iv) how the proposed research will translate prior research results into new medical therapies or test new therapies in human patients, and the projected timeline for accomplishing such clinical application(s).

4. **Resources and Environment - Limited to one (1) page.**
   A description of the facilities in which the work will be conducted and how the scientific environment will contribute to the probability of success, including such things as collaborative arrangements involving on-site resources, unique features of the subject population and support from the Applicant.

5. **Response to Reviewer Comments, if Applicable - Limited to two (2) pages.**
   For Applicants Resubmitting an application that was previously reviewed under any MSCRF funding mechanism but not funded: an Introduction to the revised Application, including the application Number of the previous MSCRF submission, and a point-by-point response to the prior scientific review.

6. **Collaboration Plan, if applicable - Limited to two (2) pages.**
   A detailed description of the nature and terms of the collaboration, and a management plan explaining such issues as how the Applicant PI and collaborator(s) will communicate and handle confidential information, use milestones to determine resource allocation and Research Project direction, share data and resources, prepare required reports and handle geographic separation, if applicable.

7. **Bioethics**: A detailed bioethics section describing the ethical issues relevant to the proposed Research Project and how these issues will be addressed, including:
   - Cell lines and ISCRO review
     - Does the proposed project use adult, embryonic, iPS or other human stem cell lines?
     - If human embryonic stem cells are involved, has the Proposal been approved by an ESCRO/SCRO Committee?
     - If an existing stem cell line is to be used, what are the justifications for that line?
     - From where will they be obtained (e.g., commercial source, laboratory and under what protocol or with what institutional approval)?
     - If new lines are to be created, what measures will be taken to comply with the Stem Cell Act, as well as existing stem cell research bioethics guidelines?
     - If human donors are involved, have they been properly consented?
     - Has an ISCRO reviewed and approved the proposed research?

   - Human subjects and IRB review
     - Will human subjects be enrolled in the proposed research?
     - If human subjects are involved, what protections will be in place to ensure their rights and welfare?

- Has IRB approval or exemption been obtained for the proposed research, or will it be?

- Nonhuman animals and IACUC review
  - Will nonhuman animals be used in the proposed research?
  - If so, what type/model will be used, sex, and what is the justification?
  - How many? What is the justification for the number to be used?
  - Has IACUC approval been received, or will it be?
  - What measures will be taken to comply with IACUC guidelines?

8. **Supporting Literature - Limited to three (3) pages.**
   Provide a list of scientific Literature in support of the Research Project.

9. **Biosketches:** Do not exceed five (5) pages for the PI and two (2) pages each for other key project personnel. NIH biosketch format is permitted as long as it meets the above page requirements.

10. **Other Support:** List Other Support for the PI, including both current and pending support as described in the instructions.

11. **Statement of Work (SoW) - Limited to one (1) page.** Applicants must use the provided template to prepare a Statement of Work that defines the project's period of performance, overall objective and scope, and the specific aims or tasks, key activities/milestones, target completion date, and measurable success criteria for each milestone. Such information is required only for each significant developmental milestone rather than for every aim listed in the application. Milestones and deliverables should be concise, measurable, and consistent with the proposed project timeline and budget.

12. **Budget and Budget Justification:** A detailed budget of the costs required to conduct the project should be provided using the template provided in the application portal. Provide a list of the names, affiliate organizations, and roles of all key personnel, in addition to the Applicant PI, who will contribute to the scientific development or execution of the Research Project in a substantive way and devote measurable effort (in person months) to the Research Project, whether or not salaries are requested. Typically, these individuals have doctoral or other professional degrees, although individuals at the master's or baccalaureate level should be included if their involvement meets the definition of key personnel. "Effort of zero person months" and "as needed" are not acceptable levels of involvement for key personnel.

    Expenses for domestic travel are capped at $5000. International travel is not an allowable expense.

    Clinical Projects require a 1:1 match of non-state funds. Indirect costs are not allowed under this RFA.

    Applicants are advised that requested salaries should not exceed fifty percent (50%) of the total project budget. Budgets should be planned accordingly.

    All expenses directed to the Research Project should adhere to the specific line items listed in the proposal. **Any budget changes or reallocation of funds between budget categories over 10% of the overall budget must be approved by MSCRF prior to reallocation.** In the event of remaining unspent funds from one installment, a carryover request must be submitted to MSCRF for approval to carry the funds to the next installment with a justification of why the funds were not used and how they will be used in the next installment.

MSCRF funds may not be used to cover personnel costs of Investigators who are located and/or conduct the work outside the State of Maryland, regardless of whether such out-of-State Investigators are employed or retained by a Maryland-based or non-Maryland based organization. Applicants are permitted to include out-of-State Investigators and/or collaborators under the Clinical Research Grant if they demonstrate that no MSCRF funds will be used to support work or personnel costs for the out-of-State Investigators.

13. **Appendix - Collaborator Letters:** The PI should include Letters of Collaboration, if applicable. A Letter of collaboration from each collaborator on university, institute, or company letterhead (i) agreeing to the proposed collaborative research; (ii) briefly outlining the nature of the collaboration; and (iii) agreeing that, if MSCRF funding is awarded, they shall share research results with each other and comply with the progress reporting duties under the MSCRF Grant Agreement, conditioned upon TEDCO's duty to maintain the confidentiality of the reported information to the extent reasonably permitted by Title 10, Subtitle 6 of the State Government Article of the Annotated Code of Maryland. Such letters must be co-signed by the collaborators and responsible officials at the collaborator's affiliate institutions. Limited to one (1) page per Collaborator.

14. **Appendix – Supporting Materials:** This section may not be used to circumvent the length limitations of the Application. Do not include information that should be in the main proposal application. Compile all supporting documents into a single PDF file.

Notes:

- The Appendix may not be used to circumvent the length limitations of the Application. Applications that are incomplete, do not meet the format and/or content requirements, exceed specified length limits, are non-responsive to this RFA, or are from ineligible Applicants will not be reviewed.

- University Applicant PIs must obtain approval from their research/grants administration office before submitting an application.

- Prior to submission, compile all documents into a single PDF file using the template provided in the applicant portal.

SUBMISSION INFORMATION

SUBMISSION DEADLINES & REVIEW DATES

- **Application Submission Deadline**: January 20, 2027, by 5:00 p.m. EST

- **Peer review date(s) and presentation by the Applicant:** Week of April 4, 2027

- **Commission Review and Announcement of Awards:** May 2027

METHODS OF SUBMISSION

The MSCRF online submission system is now open for application submissions.
Applicant PIs are encouraged to submit their application at least one week before the Application Submission Deadline. The Grant Application must be submitted by **January 20, 2027, no later than 5:00 p.m. EST**. **Late submissions will not be considered.** Applicants are advised to submit well in advance of the deadline, as technical support cannot be guaranteed for issues encountered on the submission date.

REVIEW INFORMATION

ELIGIBILITY AND COMPLIANCE REVIEW:

All applications will be initially reviewed by the MSCRF staff to ensure that they meet the minimum requirements, as specified in this RFA (the "Compliance Review"). Applications not meeting the minimum requirements will be rejected without further consideration and the applicant will be so notified. A complete submission (all sections) cannot exceed the page limit as included for each section or it will be rejected without consideration.

REVIEW PROCESS:

Following the Eligibility and Compliance Review, all Applications will be assigned by the MSCRF Scientific Review Officer (SRO) to a number of reviewers for review and preliminary scoring. All Applications, receiving average scores above a threshold determined by the Program will be brought to the full MSCRF Review Committee.

The MSCRF Review Committee will consist of representatives of the research, business and investor community and are all from outside of the state of Maryland. Each applicant will receive a copy of the reviewer comments and scores at the end of the process, whether the applicant is approved or declined for funding.

REVIEW CRITERIA:

Applicants will be evaluated on each section of their proposal listed under the application components and the applicant's ability to address each criterion listed in those sections. **Consideration will be based on how completely the applicant has provided information requested for the section and how convincingly the applicant has made a case for the opportunity based on the subject Technology.**

To receive a high impact/priority score, Applicants are encouraged to address the following categories:

- **Meeting the Overall Objectives of The MSCRF Program:** Do the proposed studies broaden and advance the knowledge of human stem cells? Does the Project address problems in regenerative medicine, as defined by the Commission? Are the studies relevant to the development of clinical application(s) to treat human diseases, injuries or conditions? Will these studies enable, support and expedite such clinical application(s)?

- **Clinical Impact:** Can the proposed research result in a therapeutic candidate that meets an unmet medical need and/or offers a competitive advantage over other therapies or devices currently in practice or in the development pipeline? Does it have the potential to significantly impact clinical treatment or medical practice?

- **Scientific Rationale:** Does the Application adequately address the scientific basis and rationale for the therapeutic candidate?

- **Readiness:** If applicable, does the data presented follow the FDA Target Product Profile TPP Guidelines, as required by the MSCRF? Does the Application adequately characterize the key product under investigation and describe in detail the production tasks required for this specific phase of development?

- **Objectives, Strategies and Milestones:** Does the research plan include appropriate, achievable objectives, feasible strategies and clearly defined milestones? Does it define and address key

issues in all areas critical to the successful progression to the next phase of the research, trial, product development or other Project objective described in the Application?

- **Likelihood of Success:** Are there limitations of the proposed studies that will make it difficult to apply findings or strategies in the clinic? Are there completed or on-going clinical trials that will impede or accelerate the proposed research?

- **Use of Human Stem Cells:** Does the proposed research use adult, embryonic, iPS or other human stem cell lines? Does the PI justify the use of human stem cells in the proposed research as necessary or advantageous as compared to other approaches?

- **Budget and Budget Justification**: Is the requested period of support appropriate for the scope of the Project? Is the effort listed for all personnel appropriate for the proposed work? Is each budget category realistic and justified in terms of the aims and methodology? If equipment is requested, is it justified, cost effective and budgeted appropriately? Is the Applicant's match adequate and appropriate for the Project? Does the Applicant provide justification for any and all proposed in-kind matches that involve existing equipment, including cost and date of acquisition as well as current usage?

- **PI and Team Leadership:** Is there evidence that the Investigators are adequately trained and well suited to carry out the Project? Is the proposed Project appropriate to the experience level of the PI and other Investigators? Does the research team bring complementary and integrated expertise to the Project?

- **Resources and Environment:** Does the scientific environment in which the work will be conducted contribute to the probability of success? Do the proposed studies benefit from any unique features of the scientific environment or subject population? Do these studies employ useful collaborative arrangements involving on-site resources or personnel? Can the Applicant provide the support and personnel necessary to complete the research?

- **Bioethics:** If an existing stem cell line is to be used, what are the justifications for that line? If new lines are to be created, what measures will be taken to comply with the Stem Cell Act as well as existing stem cell research bioethics guidelines? If animal subjects are to be used, what measures are taken to comply with IACUC guidelines? If human donors are involved, have they been properly consented? If human subjects are involved, what protections will be in place to ensure their rights and welfare? If human embryonic stem cells are involved, has the Proposal been approved by an ESCRO/SCRO Committee?

  For Applications that involve ***clinical trials***: Does the Applicant have an IND or IDE cleared by the FDA for the therapeutic candidate or device under investigation (as required by the Commission prior to submission of this Application)? Has the Proposal been approved by an IRB responsible for oversight at the Maryland facility where the trial will be conducted (as required before any MSCRF funding shall be disbursed)? Is there an independent Data Safety Monitoring Board?

- **Collaboration Plan (if applicable):** If the proposed research involves collaboration(s) among scientists and/or clinicians from for-profit and/or not-for-profit Companies and/or other organizations, is there a demonstrated commitment from each entity and a realistic management plan that addresses all potential obstacles (i.e., how the Company and collaborator(s) will communicate, handle confidential information, use milestones to determine resource re-

allocation and Project re-direction, share data and resources, prepare required reports and handle geographic separation, if applicable)?

If the PI's work was previously funded by the MSCRF, in whole or in part, the Application will be evaluated on the following additional factors: Did the Investigator make significant scientific progress towards the goals of the previously funded research? Were results of the previously funded Project reported in scientific publications and/or presented at conferences? Did the previously funded research result in new collaborations, inventions or Project-generated resources or subsequent funding from non-MSCRF sources?

SCORING:

A Scientific Peer Review Committee will review all Applications and rank them. Similar to the NIH, a scoring system of 1-9 will be used to rate the overall impact/priority of the proposed research. In this system, "1" indicates the highest impact/priority and "9" indicates the lowest impact/priority.

Project Selected for Review: All Clinical applicants who score high enough to move on to the full review committee will be required to present in person at the MSCRF Review Meetings.

- The PI and or the CEO (if not the same person) listed on the Clinical Application must plan to present on the stated review dates. Other team members may attend; however, the PI and or the CEO must attend.
- All presentations will be scheduled as part of standing MSCRF review days. Due to the number of applications on any given review day, presentation times will be assigned by MSCRF.

- The PI will need to hold the review day open until the time is assigned. This may be confirmed as close as a few days before the review day, so PIs will need to remain flexible during this process. **Applicant PI and CEO (if applicable) should plan for and secure the week of April 4, 2027 for the in-person presentation. Virtual attendance will not be considered.**
- Company PI will be required to submit the presentation directed to the Research Project to MSCRF at least 48 hours in advance of the meeting.
- Each Clinical applicant will have 15 minutes to present, followed by a timed Q&A session.
- The following are the required slides for the presentation:
    - What is the Problem?
    - What is the Solution?
        - Technology Outline
    - Target Market?
        - Segmentation Analysis
        - Target Product Profile
    - Clinical Process
        - Timeline and Costs
        - Risks and Mitigation Plan
    - Finances
        - Cost Projections
        - Financing Needed for the MSCRF Project?
        - Follow-on Financing for the Next Steps, Beyond MSCRF?
    - Management and Clinical Team
        - Advisors? Board of Directors?

- The applicant must thoughtfully address reviewers' comments in their presentation. Applicants are recommended to present no more than 10 slides.

After presentation of the preliminary scores and discussion of applications at the MSCRF Review Committee Meeting, applications will receive a final score based on an average of all the overall scores provided by the MSCRF Review Committee Members. Applications will be ranked by average final score and submitted to the Commission for review and final approval.

The Commission reserves the right to pursue collaborative funding arrangements with third parties and, in such an event, the further right to share the application materials and/or the review summaries with those potential co-funders upon the execution of a Confidentiality Agreement restricting their further disclosure.

AWARD ADMINISTRATION INFORMATION

NOTIFICATION

The PI's affiliate organization will be notified electronically when the Application is received. A formal notification, in the form of a Notice of Award ("NOA"), signed by the MSCRF Executive Director, will be sent via email to successful Applicants.

Notice of selection of an Application for award is not authorization to charge costs to the MSCRF against any award which may be made. Pre-Award costs are incurred at the Applicant's risk, and except as otherwise provided in an approved Application. Applicants may not charge pre-award costs or assume they will receive any funds until an MSCRF Grant Agreement has been fully executed by the Applicant and the MD Stem Cell Research Commission.

CLOSING AND AWARD PAYMENTS

After receiving the Notice of Award (NOA), the Applicant will be required to sign a Grant Agreement. This agreement will outline the terms and conditions of the award and specify the number of mid-term and final milestones for each project, along with the due dates for mid-term and final project reports (as described below).

Furthermore, the applicant must furnish specific regulatory compliance documents listed below before commencing the Research Project. Once these compliance documents are received and approved by MSCRF, the applicant's Principal Investigator (PI) will receive the first disbursement of funds and must promptly initiate work on the Research Project.

Regulatory Compliance Documents list:

- Institutional Review Board (IRB) approval or exemption, including the Applicant's name, project title (matching the title of the Award), and expiration date.
- Institutional Animal Care and Use Committee (IACUC) approval if animal work is to be conducted, including the Applicant's name, project title that matches the award's title, and expiration date. In the event the title of the approved IACUC protocol is different, an official letter from an authorized IACUC representative must be furnished to indicate that the animal research to be conducted under the newly awarded MSCRF Research Project is covered under that IACUC protocol.
- Stem Cell Research Committee (SCRO) approval or exemption including the Applicant's name, project title that matches the award's title, and expiration date if the research involves embryonic stem cells. In the event the title of the SCRO approval/exemption is different, an official letter from an authorized SCRO representative must be furnished to indicate that the stem cell research to be conducted under the newly awarded MSCRF Research Project is covered under that SCRO approval/exemption.

Award payments for Clinical projects will be made as follows: 50% following execution of the grant agreement and furnishing of all required regulatory documentation, and 50% upon submission and approval of a Mid-term Report and the successful completion of approved milestones. In all cases, any unused funds must be returned to MSCRF.

POST AWARD REPORTING

Clinical Program awardees must submit the following reports to the MSCRF Program:

a. **MSCRF Award Meeting** – Each awardee is required to meet with the MSCRF Award Manager at least once, prior to the mid-term. This is to assist each awardee in understanding and meeting expectations for the program. This is also an opportunity for the awardee to share feedback, discuss ideas and ask for additional assistance. The applicant can reach out to MSCRF staff at mscrfinfo@tedcomd.com email to schedule this meeting.

b. **Mid-Term Project Reports** – Each awardee is required to submit the mid-term project report ("Written Progress Report") on MSCRF portal, the link to which will be provided in advance of the submission date by MSCRF. The progress report must include a description of project activities and outcomes to date, progress toward meeting mid-term milestones, an accounting of expenditures charged to the award, and information on any deliverables, such as products, public presentations, publications, intellectual property, and follow-on funding. Additionally, each awardee must submit a PowerPoint presentation summarizing the Written Progress Report. After submitting the mid-term report and the PowerPoint presentation via the portal, MSCRF staff will schedule a meeting for the awardee to report on the progress made on the Research Project. The PI investigator must then meet with MSCRF staff to deliver a PowerPoint presentation summarizing the report's content and addressing any questions from the MSCRF team. This step is required prior to the approval of the report and the disbursement of the remaining award funds.

c. **Final Reports -** Each awardee is required to submit the final report on MSCRF portal, the link to which will be provided in advance of the submission date by MSCRF. A final report must provide an overview of all activities undertaking during the course of the funded project, a description of the results of the project, the impact on clinical outcome, the success with achieving the proposed milestones, jobs created/supported, information on any deliverables, such as products, public presentations, publications, intellectual property, follow-on funding table, and a full accounting of all expenditures charged to the award in a tabular format signed by the financial officer, as well as a formal closeout letter.

d. **Symposium presentation** - The MSCRF may conduct an in-State Annual Symposium or other related events to report to the scientific community and the public on the progress of the MSCRF program. All PIs must present, orally or in poster format, their on-going or completed MSCRF-funded research at each Annual Symposium, during and immediately following their Grant period.

COMPLIANCE

A Principal Investigator / organization not in compliance with the reporting obligations under the Clinical Research Grant shall not be eligible to apply for continued or subsequent MSCRF funding.

AGENCY CONTACTS

- Inquiries about this RFA or other programmatic matters should be submitted by email to: mscrfinfo@tedcomd.com

- Inquiries regarding technical assistance with the application and/or reporting portal should be submitted by email to: mscrfinfo@tedcomd.com